



General

Guideline Title

Practice parameters for the management of rectal cancer (revised).

Bibliographic Source(s)

Monson JR, Weiser MR, Buie WD, Chang GJ, Rafferty JF, Standards Practice Task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for the management of rectal cancer (revised). Dis Colon Rectum. 2013 May;56(5):535-50. [154 references]
[PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Tjandra JJ, Kilkenny JW, Buie WD, Hyman N, Simmang C, Anthony T, Orsay C, Church J, Otchy D, Cohen J, Place R, Denstman F, Rakinic J, Moore R, Whiteford M. Practice parameters for the management of rectal cancer (revised). Dis Colon Rectum. 2005 Mar;48(3):411-23.

Recommendations

Major Recommendations

The levels of evidence and the grades of recommendations (1A-2C) are defined at the end of the "Major Recommendations" field.

Preoperative Assessment

A. Evaluation and Risk Assessment

1. A thorough disease history should be obtained eliciting disease-specific symptoms, associated symptoms, and family history. Routine laboratory values, including carcinoembryonic antigen (CEA) levels should also be evaluated, as indicated. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
A complete family medical history should be obtained to guide the surgeon to suspect hereditary cancer syndromes and look for associated pathology. Patients meeting clinical criteria for or having a family history of an increased susceptibility to colorectal cancer should be referred for genetic counseling for formal evaluation and possible testing.

Routine laboratory examinations including complete blood cell counts, liver function tests, and chemistry panel should be performed based on patient comorbidities as indicated for preparation for general anesthesia. CEA levels should be assessed before elective treatment of rectal cancer for the establishment of baseline values and during the surveillance period to monitor for signs of recurrence.

2. As part of a full physical examination, proctosigmoidoscopy should be performed in conjunction with a digital rectal examination (DRE) to determine the distance of the lesion from the anal verge, mobility, and to assess its position in relation to the sphincter complex. Grade of Recommendation: Strong recommendation based on low quality evidence, 1C.
Clinical evaluation by DRE can be informative regarding the degree of tumor fixation and location and should be performed in conjunction with formal clinical staging by ultrasound or magnetic resonance imaging (MRI). Proper identification of the tumor location also permits treatment stratification for sphincter preservation or for the assessment of treatment benefit from neoadjuvant therapy.
3. When possible, all patients with rectal cancer should undergo a full colonic evaluation with histological assessment of all colorectal lesions before treatment. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
Complete assessment of the colon should be performed (preoperatively or postoperatively) because the incidence of synchronous cancers is 1% to 3%, and the incidence of synchronous polyps is 30%. In the case of an incomplete colonoscopy, a double-contrast barium enema or computed tomography (CT) colonography may be used preoperatively. If preoperative colon evaluation is not feasible, early postoperative evaluation (within 3 to 6 months) is reasonable.

Histological diagnosis should be confirmed before elective resection. This is particularly true if neoadjuvant therapy is being considered. For lesions amenable to local excision, with nondiagnostic initial biopsy results, information may be obtained at the time of transanal excision. Subsequent surgical management should be guided by the resultant histopathological findings.

B. Staging

1. Rectal cancer staging should be routinely performed according to the American Joint Committee on Cancer tumor, node, metastasis (TNM) system with assignment of both pretreatment clinical and posttreatment pathological stage. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
The TNM system, as defined by the American Joint Committee on Cancer, is the most commonly used system and is based on the depth of local tumor invasion (T stage), the extent of regional lymph node involvement (N stage), and the presence of distant metastasis (M stage) (see Tables 2 and 3 in the original guideline document).

Staging for rectal cancer should consider both the clinical stage (upon which subsequent treatment decisions are made) and the final pathological stage, which may represent the most important prognostic factor in rectal cancer. Increasing use of preoperative treatment has led to the requirement that the pathological staging may incorporate a "downstaging" effect and the prefix "y" is attached to the pathology report (designated "p") to reflect previous multidisciplinary treatment. Preoperative staging should also be prefixed by the staging modality including c for clinical, u for ultrasound, mr for MRI, and ct for CT scan.

2. Clinical staging of the primary tumor by endorectal ultrasound (EUS) or dedicated high resolution rectal MRI should be performed. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
EUS with rigid or flexible probes and MRI with either endorectal or increasingly phase array coils are the primary tumor-staging modalities of choice. EUS is less accurate in the assessment of large bulky lesions (T4 stage accuracy of 44%–50%), and stenotic lesions can pose difficulties because the probe may be unable to traverse the lesion, leading to suboptimal staging.

MRI is particularly useful in the evaluation of the circumferential margin (CRM). Findings on pretreatment MRI can therefore be used for surgical planning. Although MRI is useful in the preoperative staging of rectal cancer, specific protocols have been developed for this utility.

3. All patients with rectal cancer should have preoperative radiological staging to assess for metastatic disease. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
Preoperative radiographic staging including a CT scan of the chest, abdomen, and pelvis should be routinely performed before the elective surgical resection of rectal cancer. A CT scan of the chest is more sensitive than a chest x-ray for detecting pulmonary metastases.

Alternative imaging strategies for patients with contrast dye allergies may include an MRI of the abdomen and pelvis with a non-contrast-enhanced chest CT or fluorodeoxyglucose-positron emission spectroscopy (FDG-PET) imaging. However, the role of FDG-PET/CT imaging is currently still evolving.

C. Preparation for Surgery

1. When an ostomy is a consideration, preoperative counseling should be obtained with marking of the proposed ostomy site. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
Preoperative assessment and ostomy site determination by an enterostomal therapist improves outcomes in patients who require a

stoma. Intensive preoperative teaching has been shown to improve time to ostomy proficiency, reduce hospital length of stay, and realize a significant cost savings.

Treatment

Surgery should be performed by surgeons with special knowledge, training, and experience in the management of rectal cancer. Patients with low-risk, early-stage disease are typically treated with primary surgical therapy. Treatment of locally advanced or high-risk disease requires a multidisciplinary approach to include neoadjuvant radiation or chemoradiation followed by surgery.

A. Surgical Techniques and Operative Considerations

Local Excision

1. Local excision is an appropriate treatment modality for carefully selected T1 rectal cancers without high-risk features. Grade of Recommendation: Weak recommendation based on moderate quality evidence, 2B.
Local excision can be performed via transanal excision (Parks-type excision) or with a transanal endoscopic microsurgery approach. The transanal endoscopic microsurgery approach appears to be superior to the transanal approach in terms of visualization and resection of higher lesions.

The technique involves a full-thickness excision of the lesion down to perirectal fat, with a macroscopically normal margin of 10 mm. The excised segment should be orientated for pathological examination.

Radical Excision

1. A thorough surgical exploration should be performed and the findings documented in the operative report. Grade of Recommendation: Strong recommendation based on low quality evidence, 1C.
2. Total mesorectal excision (TME) should be used for curative resection of tumors of the middle and lower thirds of the rectum, either as part of low anterior or abdominoperineal resection. For tumors of the upper third of the rectum, a tumor-specific mesorectal excision should be used with the mesorectum divided ideally no less than 5 cm below the lower margin of the tumor. Grade of Recommendation: Strong recommendation based on high quality evidence, 1A.
3. A 2-cm distal mural margin is adequate for most rectal cancers when combined with a TME. For cancers located at or below the mesorectal margin, a 1-cm distal mural margin is acceptable. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
4. Proximal vascular ligation at the origin of the superior rectal artery with resection of all associated lymphatic drainage is appropriate for most rectal cancer resections. Grade of Recommendation: Strong recommendation based on high quality evidence, 1A.
5. In the absence of clinical involvement, extended lateral lymph node dissection (LLND) is not necessary in addition to TME. Grade of Recommendation: Strong recommendation based on weak quality evidence, 1C.
6. Patients with an apparent complete clinical response to neoadjuvant therapy should be offered a definitive resection. Grade of Recommendation: Strong recommendation based upon moderate quality evidence, 1B.
At the present time a policy of observation should be reserved for patients who are not fit for or who refuse radical surgery.
7. After low anterior resection and TME, the formation of a colonic reservoir may be considered. Grade of Recommendation: Weak recommendation based on moderate quality evidence, 2B.
Various surgical techniques have been developed, including colonic J-pouch, transverse colectomy, and the side-to-end anastomosis, to improve postoperative function.
8. Intraoperative anastomotic leak testing should be performed to help identify an anastomosis at increased risk of a subsequent clinical leak. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
Options for intraoperative correction of the leak include suture repair, repeat anastomosis, or repair with proximal diversion.
9. A diverting ostomy should be considered for patients undergoing a TME for rectal cancer. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.
A diverting ostomy can be either a diverting loop colostomy, typically of the transverse colon, or a diverting loop ileostomy. The loop ileostomy is preferred over loop colostomies because of the ease in reversal; however, loop ileostomies have been associated with an increased incidence of high stoma output and dehydration.
10. In patients undergoing a TME, an intraoperative rectal washout may be considered. Grade of Recommendation: Weak recommendation based on low quality evidence, 2C.
11. In patients with T4 rectal cancers, resection of involved adjacent organs should be performed with an en bloc technique. Grade of

Recommendation: Strong recommendation based on moderate quality evidence, 1B.

Patients with such advanced disease should undergo a thorough preoperative evaluation to assess resectability and a role for neoadjuvant therapy.

12. Current evidence indicates that laparoscopic TME can be performed with equivalent oncological outcomes in comparison with open TME when performed by experienced laparoscopic surgeons possessing the necessary technical expertise. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.

13. Oophorectomy is advised for grossly abnormal ovaries or contiguous extension of a rectal cancer, but routine prophylactic oophorectomy is not necessary. Grade of Recommendation: Strong recommendation based on low quality evidence, 1C.

B. Tumor-related Emergencies

1. In patients with large-bowel obstruction, an expanding stent is an acceptable treatment option in the palliative setting or as a bridge to definitive resection. Grade of Recommendation: Strong recommendation based on low quality evidence, 1C.

A proximal diverting ostomy is effective in relieving obstruction secondary to a rectal tumor in patients who are not candidates for stent placement, or in a center where it is not available. A diverting loop ostomy with a distal efferent limb should be used in a patient with complete obstruction to allow for distal venting.

C. Multimodality Therapy

Neoadjuvant Therapy

1. Neoadjuvant therapy should be used for locally advanced cancers of the mid or distal rectum. Grade of Recommendation: Strong recommendation based on high quality evidence, 1A

There are 2 possible approaches to delivering neoadjuvant therapy: short-course radiotherapy (SCRT) using 5 Gray (Gy) daily over 5 days without chemotherapy followed by surgery within 1 week and "long-course" preoperative chemoradiotherapy (LCCRT) using conventional doses of 1.8 to 2 Gy per fraction over 5 to 6 weeks to a total dose of 45 to 50.4 Gy with concurrent administration of 5-fluorouracil (5-FU)-based chemotherapy followed by surgery 8 to 12 weeks later.

D. Adjuvant Therapy

1. Adjuvant chemoradiotherapy should be recommended for select patients with stage III or high-risk stage II rectal cancer who have not received neoadjuvant therapy. Grade of recommendation: Strong recommendation based upon moderate quality evidence, 1B.
2. Adjuvant chemotherapy should be recommended for patients with high-risk stage II and all stage III disease previously treated with neoadjuvant therapy. Grade of Recommendation: Strong recommendation based upon high quality evidence, 1A.

E. Documentation

1. The surgical report should include information regarding the diagnostic workup, intraoperative findings, and technical details of the procedure. Grade of Recommendation: Strong recommendation based on low quality evidence, 1C.
Preoperative information should include comments on the histological confirmation of malignancy, the estimated stage of the tumor based on preoperative imaging, the estimated level of the tumor in the rectum, and confirmation that an ostomy site has been preoperatively marked. The report should also include a description of preoperative treatments.
2. Accurate, detailed, and consistent pathology reporting is integral in the estimation of patient prognosis and treatment planning in rectal cancer. It is recommended that the elements described in the College of American Pathologists guidelines on Protocol for the Examination of Specimens from Patients with Primary Carcinomas of the Colon and Rectum be reported. Grade of Recommendation: Strong recommendation based upon low quality evidence, 1C.

Definitions:

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) System—Grading Recommendations^a

1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence	Strong recommendation, can apply to most patients in most circumstances without

	evidence		from observational studies	reservation
1C	Strong recommendation, low- or very-low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendations, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, low- or very-low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

RCT = randomized controlled trial

^aAdapted from Guyatt G, Guterma D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians Task Force. Chest. 2006;129:174–181.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Rectal cancer

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Colon and Rectal Surgery

Gastroenterology

Internal Medicine

Oncology

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide appropriate recommendations for management of patients with rectal cancer

Target Population

Patients with rectal cancer

Interventions and Practices Considered

Evaluation

Preoperative Assessment

1. History and physical examination
 - Laboratory testing, including liver function and carcinoembryonic antigen levels
 - Proctosigmoidoscopy in conjunction with a digital rectal examination
 - Full colonic evaluation with histological assessment
2. Clinical staging according to tumor, node, metastasis (TNM) classification
 - Endorectal ultrasound (EUS)
 - High resolution magnetic resonance imaging (MRI)
 - Preoperative staging with computed tomography (CT) scanning of the chest, abdomen and pelvis
3. Preoperative counseling

Treatment/Management

Surgical Techniques and Operative Considerations

1. Local excision
2. Radical excision
 - Surgical exploration
 - Total mesorectal excision (TME)
 - Determination of resection margins
 - Proximal vascular ligation dissection (not recommended)
 - Formation of colonic reservoir
 - Intraoperative anastomotic leak testing
 - Extended lateral lymph node
 - Diverting ostomy
 - En bloc resection (for adjacent organ involvement)
 - Oophorectomy if indicated
3. Emergency expanding stent or diverting ostomy

4. Detailed surgical and pathology reporting

Multimodality Therapy

1. Neoadjuvant therapy
 - Short-course radiotherapy
 - Long-course preoperative chemoradiotherapy
2. Adjuvant chemotherapy

Major Outcomes Considered

- Morbidity and mortality
- Tumor recurrence rate
- Sensitivity and specificity of diagnostic tests
- Survival and disease-free survival

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

These guidelines are built on the last set of the American Society of Colon and Rectal Surgeons Practice Parameters for treatment of rectal carcinoma published in 2005. An organized search of MEDLINE, PubMed, EMBASE, and the Cochrane Database of Collected Reviews was performed through February 2012. Key-word combinations included rectal cancer, total mesorectal excision (TME), radiotherapy, chemotherapy, endorectal ultrasound, magnetic resonance imaging (MRI), and enterostomy. Directed searches of the embedded references from the primary articles were also performed in selected circumstances.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

See the "Rating Scheme for the Strength of the Recommendations" field, below.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These guidelines are built on the last set of the American Society of Colon and Rectal Surgeons Practice Parameters for treatment of rectal carcinoma published in 2005.

Recommendations were formulated by the primary authors and reviewed by the entire Standards Committee. The final grade of recommendation was performed with the use of the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) system.

Rating Scheme for the Strength of the Recommendations

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) System—Grading Recommendations^a

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Cost Analysis

The guideline developers reviewed a published cost analysis.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each of the recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate evaluation and management of patients with rectal cancer
- A greater understanding of the disease process, more accurate radiological staging, multimodality therapeutic intervention, refined surgical techniques, and more detailed histopathological reporting contribute to improvements in the management and survival of patients.
- Proper identification of the tumor location permits treatment stratification for sphincter preservation or for the assessment of treatment benefit from neoadjuvant therapy.

Potential Harms

- Compared with surgery alone, patients who received short-course radiotherapy (SCRT) did experience more gastrointestinal (GI) complications and had a higher rate of hospitalization over the 6-month period following surgery.
- The combination of neoadjuvant radiotherapy and total mesorectal excision (TME) surgery may result in significant long-term side effects including chronic bowel dysfunction, sphincter dysfunction, and sexual dysfunction.
- Although some authors have questioned the need for radical excision, a major concern regarding this approach is the ability to accurately predict a complete pathological response. Neither clinical examination involving digital rectal examination (DRE) nor current imaging modalities (magnetic resonance imaging [MRI], computed tomography [CT], or positron emission tomography [PET] scanning) can reliably predict pathological complete response such that radical surgery can be avoided. This issue will only be resolved by a randomized trial. At the present time a policy of observation should be reserved for patients who are not fit for or who refuse radical surgery.
- Adverse events including tumor perforation should be clearly documented, because tumor perforation is associated with a significant increase in the risk of local recurrence and a reduction in 5-year survival.
- The loop ileostomy is preferred over loop colostomies because of the ease in reversal; however, loop ileostomies have been associated with an increased incidence of high stoma output and dehydration.
- Functional problems, including urgency, increased bowel frequency, clustering, and fecal incontinence, occur after a low anterior resection and are attributed, in part, to the loss of the reservoir function of the rectum.
- The incidence of anastomotic leak ranges from 3% to 32% with the range possibly accounted for by differences in patient populations, surgical technique, formation of a diverting ostomy, and use of radiological modalities to look for an anastomotic leak.
- Viable exfoliated malignant cells have been demonstrated in the lumen of patients with primary rectal cancer. Circular stapling devices for low colorectal anastomosis may provide a mechanism by which tumor cells are collected and subsequently implanted at the site of the

anastomosis.

- Patients with a positive circumferential margin following TME surgery are at high risk for local recurrence and should be considered for additional treatment.

Qualifying Statements

Qualifying Statements

- These guidelines are inclusive, and not prescriptive. Their purpose is to provide information on which to base decisions, rather than dictate a specific form of treatment. These guidelines are intended for the use of all practitioners, health care workers, and patients who desire information about the management of the conditions addressed by the topics covered in these guidelines.
- It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Monson JR, Weiser MR, Buie WD, Chang GJ, Rafferty JF, Standards Practice Task Force of the American Society of Colon and Rectal

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1993 (revised 2013 May)

Guideline Developer(s)

American Society of Colon and Rectal Surgeons - Medical Specialty Society

Source(s) of Funding

American Society of Colon and Rectal Surgeons

Guideline Committee

Standards Practice Task Force of the American Society of Colon and Rectal Surgeons

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Endorser(s)

Society for Surgery of the Alimentary Tract, Inc - Medical Specialty Society

Society of Surgical Oncology - Medical Specialty Society

Guideline Status

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [American Society of Colon and Rectal Surgeons \(ASCRS\) Web site](#)

Print copies: Available from the American Society of Colon and Rectal Surgeons, 85 W. Algonquin Road, Suite 550, Arlington Heights, Illinois 60005.

Availability of Companion Documents

None available

Patient Resources

The following are available:

- Colorectal cancer. Available in [English](#) and [Spanish](#) from the American Society of Colon and Rectal Surgeons (ASCRS) Web site.
- Colorectal cancer surgery - follow up evaluation. Available from the [ASCRS Web site](#) .

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NGC Status

This summary was completed by ECRI on February 15, 2000. The information was verified by the guideline developer on November 7, 2000. This summary was updated by ECRI on July 15, 2005. This NGC summary was updated by ECRI Institute on September 13, 2013.

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